Yale University

Ralph I. Horwitz, M.D.
Chairman
Department of Internal Medicine
Harold H. Hines, Jr. Professor of
Medicine and Epidemiology
School of Medicine

Campus address:
1072 LMP
333 Cedar Street
P.O. Box 208056
New Haven, Connecticut 06520-8056
Telephone: 203 785-4119
Fax: 203 785-6954

Chief, Beeson Medical Service Yale-New Haven Hospital 20 York Street New Haven, Connecticut 06510-3202

May 10, 2000

Dockets Management Branch (HFA-305) Food and Drug Administration 5630 Fishers Lane, Room 1061 Rockville, Maryland 20852

By Federal Express

RE: The Final Ren

The Final Report of The Hemorrhagic Stroke Project Docket No. 76N-052N

To whom it may concern:

On instruction from Dr. Charles Ganley (Director, Division of Over-the-Counter Drug Products) I am submitting this letter to indicate that a document titled, "Phenylpropanolamine & Risk of Hemorrhagic Stroke: Final Report of the Hemorrhagic Stroke Project" has been submitted to Docket No. 81N-0022.

Sincerely,

Ralph I. Horwitz

cc: Lorna C. Totman, Ph.D.
Director of Scientific Affairs
Consumer Healthcare Products Association
1150 Connecticut Avenue, N.W.
Washington, DC 20036-4193

Charles J. Ganley, M.D.
Director, Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Boulevard
Document Control Room – S212
Rockville, Maryland 20850

HSP investigators and members of the Scientific Advisory Group

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